



REVISED INTERIM UTILITY GUIDELINES TRAINING
MATERIALS

Contents

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NOV 05 2003

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3) Is the asserted utility specific? The answer to this question is yes. In this case, the monoclonal antibody is specific for a specific protein, namely receptor A. Therefore, there is an asserted specific utility for the claimed invention.

4) Is the asserted utility substantial? The answer to this question is no. Specifically, since neither the specification nor the art of record disclose any diseases or conditions associated with receptor A, the asserted utility in this case is a method of treating an unspecified, undisclosed disease or condition, which does not define a "real world" context of use. Treating an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. *See Brenner v. Manson*, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

Thus, both a 35 U.S.C. § 101 rejection and a 35 U.S.C. § 112, first paragraph, utility rejection should be made on claim 3.

Caveat:

Let us assume for the moment that the specification also discloses that receptor A is present on the cell membranes of melanoma cells but not on the cell membranes of normal skin cells. Assume also that the examiner has found and made of record a journal article published prior to the

application's filing date indicating that it is desirable to selectively detect melanoma cells as opposed to normal skin cells so as to diagnose that type of cancer. Does this change the above analysis?

For each of the claims, the above analysis changes right from the first question: Based on the record, is there a "well established utility" for the claimed invention? The answer to this question would change to yes in each case. Specifically, based on this record, there is a "well established utility" for the products of claims 1 and 3. The "well established utility" for the receptor A is a method of assaying for materials that bind to receptor A by contacting the materials to a complex of receptor A and protein X. Furthermore, making a monoclonal antibody to receptor A for diagnosing melanoma would constitute a well-established utility. Such utilities are "well established" because the disclosure of the properties of the receptor and antibody taken together with the knowledge of one skilled in the art indicates that these specific, substantial and credible utilities were known. With respect to claim 2, since there is now evidence of record providing a correlation between this method and diagnosing melanoma, i.e., materials identified by the method, such as the monoclonal antibody, can be used to diagnose melanoma, this method now has a "well established utility".

Therefore, utility rejections under 35 U.S.C § 101 rejection and a 35 U.S.C. § 112, first paragraph, should not be made against claims 1-3.